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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/192,336	02/04/94	HUANG	W ETH966

EXAMINER	
WHITE, E	

ART UNIT	PAPER NUMBER
1803	4

18M1/0915

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DATE MAILED: 09/15/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire Three month(s), ~~_____ days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 18 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 - 18 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

SN-08/192,336

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Claims 1-15 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-14 of copending application Serial No. 07/680,955. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 16 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending application Serial No. 07/680,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 16 and 17 of Application Serial No. 08/192,336 appear to disclose limitation of the composition used in the method of reducing the incidence of post-operative adhesion formation in an animal which is broadly encompassed in the composition used in the method claimed in Application Serial No. 07/680,955.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section

102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 18 is rejected under 35 U.S.C. § 103 as being unpatentable over Chemical Abstracts (114 (10):88722t A. Galatik, "Pharmaceutical preparation based on hyaluronic acid alkali metal salt complexes with multivalent metals") and Derwent (AN 79-32582B abstract of JP-A-54036388 (SUBMITOMO ELEC.IND.KK)) in view of Balazs (US Patent No. 4,141,973).

Applicants claim an adhesion preventative comprising a steriled non-inflammatory hyaluronic acid fraction having a weight average molecular weight of in the range of from about 550,000 to about 8,000,000 having carboxyl acid groups which are ionically crosslinked by at least one trivalent cation selected from the group consisting of iron, aluminum and chromium wherein

in the range of from about 60 to about 100 percent of the carboxyl acid group have been ionically crosslinked by said trivalent cations and the adhesion preventative has a viscosity of at least 2,500 cps.

The Chemical Abstracts Reference No. 88722t discloses a pharmaceutical solution for use in human and veterinary medicine containing .02-3 wt% of complexes of hyaluronic acid alkali metal salts with cations which may be selected as Al3+, Cr3+ or Fe3+, at 0.1-5 mol hyaluronate to 1-25 mol coordination cation.

The Derwent Abstract Reference No. 79-32582B discloses an acidic polysaccharide which may be made insoluble in water by using a crosslinking agent which may be a polyvalent metal ion whereby the polysaccharide may be hyaluronic acid.

The Balazs Patent, which discloses molecular weights and viscosity values of hyaluronic acid, is cited to show that the average molecular weights in the range of from about 550,000 to about 8,000,000 and viscosity values of hyaluronic acid from about 2,500 cps to about 250,000 cps are well known in the art (see column 4, lines 44-57 of the Balazs Patent).

It is noted that Applicants refer to the composition of Claim 18 as an adhesion preventative. Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89(CCPA, 1982); In re Pearson, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and In re Hack 114 USPQ 161.

It would have been obvious to one having ordinary skill in

the art at the time the invention was made to modify the hyaluronic composition comprising a trivalent cation as disclosed in the Chemical Abstract and Derwent Abstract by using a hyaluronic acid having a molecular weight within the range from about 550,000 to about 8,000,000 and viscosity values of hyaluronic acid within the range from about 2,500 cps to about 250,000 cps as taught by Balazs since Balazs suggests that the use of hyaluronic acid having such properties for the treatment of injuries to connective tissues is well known in the art.

All the claims (Claims 1-18) are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

EW
White
September 12, 1994

ELLI PESELEV
PATENT EXAMINER
ART UNIT 183